DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
Telephone: 781.596.7700
Facsimile: 781.596.7899

August 1, 2003

WARNING LETTER

NWE–23–03W

CERTIFIED MAIL
RETURN RECEIPT

Mr. Ronald Sidman, Chairman of the Board
Chief Executive Officer, and President
The First Years, Inc.
1 Kiddie Drive
Avon, Massachusetts 02322

Dear Mr. Sidman:

We are writing to you because on May 6, 2003, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as Natural Comfort™ breast pump, Catalog/Model No. 1075, which is made and marketed by your firm.

Under a United States law, the Federal Food, Drug and Cosmetic Act, this product is considered to be a medical device because it is intended to affect a structure or function of the human body. (See FDCA section 201(h), 21 U.S.C. 321(h).) The law requires that manufacturers of medical devices obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your automatic suction release cycle breast pump for sale. FDA has determined that this electronic control pump is significantly different from the manual suction release breast pump that was found to be substantially equivalent under Section 510(k), K964403. Under a federal regulation, 21 CFR 807.81(a)(3)(i), this change from manual suction release, as found on your cleared breast pump, to automatic suction release requires the submission of a new premarket notification because it involves major modifications to the technology or performance of the device. The kind of information you need to submit in order to obtain this clearance is described on FDA's device web site at www.fda.gov/cdrh/devadvice. FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from the FDA, marketing your modified product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is misbranded under the Act because you did not submit a section 510(k) premarket notification that shows your modified device is substantially equivalent to another device that is legally marketed. Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that your device is substantially equivalent to another legally marketed device and therefore that you may market your device, your modified product is also adulterated under the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1–800–638–2041 or through the Internet at www.fda.gov/cdrh/dsma/dsmastaf.html.

It is necessary to take action on this matter now. Please let this office know what steps you have taken to correct the problem within fifteen (15) working days from the date you receive this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Mark Lookabaugh, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, 4th

Floor, Stoneham, MA 02180. If you have any questions concerning this matter, please contact Mr. Lookabaugh at 781-596-7751.

Sincerely,

for

Gail Costello
Director
New England District